K012283

OCT - 1 2001

510(k) Summary of Safety and Effectiveness For SOLOGARD® LOCKING PLUS Syringe with Needle

July 18, 2001

CONTACT PERSON:

Patrick Grant, Jr.
SafeGard Medical Products, Inc.
52 Dragon Court
Woburn, MA 01801
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DEVICE NAME:

Trade name: SOLOGARD® LOCKING PLUS Syringe with Needle
Common & Classification name: Piston Syringe

PREDICATE DEVICES:

Becton Dickinson Single Use Hypodermic Syringes and SafeGard Medical Products, Inc. SOLOGARD® LOCKING PLUS Syringe without Needle

PRODUCT DESCRIPTION:

The SOLOGARD® LOCKING PLUS Syringe is a sterile, single-use, disposable hypodermic syringe with a plunger locking feature to prevent the accidental reuse of the syringe. It is manufactured in sizes of 1, 2.5, 3, 5, & 10 ml and is supplied with a G29 x ½" or G29 x 5/8" needle.

INTENDED USE:

The syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.

COMPARISON TO PREDICATE DEVICES:

The SOLOGARD® LOCKING PLUS Syringe with needle is designed with a locking feature which detains the plunger after it is depressed and prevents the plunger withdrawal for a subsequent accidental reuse. In this aspect it is similar to the predicate SOLOGARD® LOCKING PLUS Syringe without Needle.

All other aspects of the design do not vary significantly from the predicate Becton Dickinson device.

EQUIVALENCE:

The performance and use of this device do not differ significantly from the predicate devices. Therefore, SafeGard Medical Products, Inc. believes that this device is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Mr. Patrick Grant, Jr.
President
Safegard Medical Products, Incorporated
52 Dragon Court
Woburn, Massachusetts 01801

Re: K012283
Trade/Device Name: Sologard Locking Plus Syringe with Needle
Regulation Number: 880.5860 and 880.5570
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF and FMI
Dated: July 18, 2001
Received: July 20, 2001

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012283

Device Name: SOLOGARD® Locking Plus Syringe with Needle

Indications For Use:

These syringes are intended for use by health care professionals for general purpose fluid aspiration/injection. The devices contain a piston locking mechanism which aids in the prevention of the accidental reuse of the syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012283

(Optional Format 1-2-96)